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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/801,276	03/07/2001	Ulrich Haueter	14018	5513

25763 7590 01/06/2004

DORSEY & WHITNEY LLP
INTELLECTUAL PROPERTY DEPARTMENT
50 SOUTH SIXTH STREET
MINNEAPOLIS, MN 55402-1498

EXAMINER

JEFFERY, JOHN A

ART UNIT PAPER NUMBER

3742

DATE MAILED: 01/06/2004

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/801,276

Applicant(s)

HAUETER ET AL.

Examiner

John A. Jeffery

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-39 and 42-49 is/are rejected.
- 7) ☒ Claim(s) 40 and 41 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 March 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claims 38 and 41 are objected to because of the following informalities:

Claim 38: In line 1, "process" must be changed to "processor." Appropriate correction is required.

New Matter

The amendment filed 12/2/03 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

Newly-added claims 47 and 48 call for the remote terminal determining body hormone level and temperature respectively by measuring the angular position of the stepper motor. The original disclosure, however, did not teach nor suggest such a calculation. The only reference to such measurements in the instant specification is on Page 11, third full paragraph.

As best understood by the examiner, the measurement value is not determined by the motor position, but rather via conventional sensors. For examination purposes,

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the examiner presumes that such measurement values are obtained via sensors -- not via the motor position.¹

Applicant is required to cancel the new matter in the reply to this Office Action.

Claims 47 and 48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 34, 37, 42, 46, 48, and 49 are rejected under 35 USC 102(e) as being anticipated by Levitas et al (US 5,895,371). Levitas et al (US 5,895,371) discloses a

¹ If, however, the sensed motor position somehow detects body hormone levels and temperatures, applicant must provide adequate written description to support such a feature to enable one of ordinary skill in the art to make and/or use such a feature. The specification as originally filed is not enabling for these features.

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remotely-controlled fluid administration device comprising an infusion pump 12 that takes measurement values related to the fluid administration and transmits such values to a remote terminal 20. The remote terminal 20 not only displays the administration device's operating parameters, but also remotely controls the administration device via a control signal. See Figs. 1-4, col. 4, lines 42-68, and col. 10, lines 19-38. Regarding claim 48, note thermometer 40.

Claim Rejections - 35 U.S.C. § 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 35, 36, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levitas et al (US 5,895,371). The claims differ from the previously cited prior art in calling for a fluid ampoule driven by a controlled piston. Levitas et al (US 5,895,371) discloses dispensing the fluid by a pump motor 124 driving a pumping mechanism 126. The motor is controlled by sensing the shaft position. See col. 4, lines 42-68. Such a control scheme ensures the motor speed corresponds to the desired infusion rate. In view of Levitas et al (US 5,895,371), it would have been obvious to one of ordinary skill in the art to provide a control system for the mechanical fluid dispensing

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means of the previously described apparatus to automatically control the infusion of fluid responsive to the motor shaft position -- a parameter that can be detected easily using conventional sensors such as encoders.

Although Levitas et al (US 5,895,371) does not disclose a piston, the reference teaches using a "pumping mechanism" such as a rotary pump wheel. Col. 4, lines 42-47. The specific mechanical means to dispense fluid is not seen to be critical and is therefore not patentably distinguishable from the remotely-controlled dispensing means of Levitas et al (US 5,895,371).

Regarding claim 36, the use of handheld computers, such as notebook computers, PDAs, and the like, are well known in the art to facilitate portable data processing and display and do not constitute a patentably distinguishable feature of the invention.

Claims 39 and 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levitas et al (US 5,895,371) in view of EP98592. The claims differ from the previously cited prior art in calling for an audible malfunction alarm. Although Levitas et al (US 5,895,371) teaches providing an alarm upon sensing a malfunction in col. 6, lines 15-30 and col. 8, lines 1-10, the reference is silent as to whether the alarm acoustically alerts the user. But providing an audible malfunction alarm in a remotely-controlled fluid dispenser is conventional and well known in the art as evidenced by EP98592 noting audible alarm 8 on Page 17, lines 5 and 6. Such an alert informs the user of a system anomaly without the need for the user to be within sight of the device (i.e., the user can

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be at a distance). In view of EP98592, it would have been obvious to one of ordinary skill in the art to provide an audible acoustic alarm in the previously described apparatus to inform the user of a system anomaly without the need for the user to be within sight of the device.

The claims also differ from the previously cited prior art in calling for the fluid to be insulin and the measurement value to be glucose concentration. But measuring glucose concentration and controlling an insulin dispenser responsive to such a measurement is conventional and well known in the art as evidenced by EP98592 noting the abstract where an insulin injection unit is automatically controlled based on the detected glucose concentration. See also Figs. 1 and 3 and P. 7, line 15 - P. 8, line 18. Such a feature provides automatic treatment of diabetes patients. In view of EP98592, it would have been obvious to one of ordinary skill in the art to inject insulin automatically responsive to sensed glucose in the previously described apparatus to automatically normalize blood sugar levels of diabetes patients.

The claims also differ from the previously cited prior art in calling for wireless transmission. But wirelessly transmitting sensed data in an automatic dispensing apparatus is well known in the art as evidenced by EP98592 where the glucose concentration is wirelessly communicated to the computer 4 via radio transmitter 11. Moreover, wireless transmission enables remote control from any location thus precluding the need to be near telephone wires or other communications wiring. In view of EP98592, it would have been obvious to one of ordinary skill in the art to provide wireless communications capability in the previously described apparatus to enable

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remote control from any location thus precluding the need to be near telephone wires or other communications wiring.

Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Levitas et al (US 5,895,371) in view of Usala (US5776324). The claim differs from the previously cited prior art in calling for detecting hormone levels. The use of biosensors to detect either glucose or hormone levels is conventional and well known in the art as evidenced by Usala (US5776324) noting col. 7, lines 40-51. As noted in col. 6, lines 28-48, such hormones include biological substances secreted by certain tissues. In view of Usala (US5776324), it would have been obvious to one of ordinary skill in the art to provide a capability to detect hormones in the previously described apparatus so that biological substances secreted by certain tissues could be detected thereby detecting biological substances in addition to blood glucose levels.

Allowable Subject Matter

Claims 40 and 41 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Other Pertinent Prior Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Applicant should (1) separately consider the art, and (2) consider

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the art together with the previously cited prior art for potential applicability under 35 U.S.C. §§ 102 or 103 when responding to this action. US 869, US 245, US 336, US 533 disclose remotely-controlled infusion devices relevant to the instant invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John A. Jeffery whose telephone number is (703) 306-4601. The examiner can normally be reached on Monday - Thursday from 7:00 AM to 4:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ehud Gartenberg, can be reached on (703) 308-2634. All faxes should be sent to the centralized fax number at (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

A handwritten signature in black ink, appearing to read "John A. Jeffery", with a stylized flourish at the end.

**JOHN A. JEFFERY
PRIMARY EXAMINER**

12/31/03